immediately retrieved from another location by electronic means shall be considered as meeting the requirements of this paragraph.

(m) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming are used, suitable reader and photocopying equipment shall be readily available.

(n) Production control, product testing, testing results, complaints, and distribution records necessary to verify compliance with parts 106, 107, 109, 110, and 113 of this chapter, or with other appropriate regulations, shall be retained for 1 year after the expiration of the shelf life of the infant formula or 3 years from the date of manufacture, whichever is greater.

(o) The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any batch of infant formula.

[56 FR 66571, Dec. 24, 1991; 57 FR 7435, Mar. 2, 1992]

Subpart D—Notification Requirements

§ 106.120 New formulations and reformulations.

(a) Information required by section 412(b)(2) and (3) of the act shall be submitted to Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.

(b) The manufacturer shall promptly notify the Food and Drug Administration when the manufacturer has knowledge (as defined in section 412(c)(2) of the act) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer may not provide the nutrients required by section 412(g) of the act and by regulations promulgated under section 412(a)(2) of the act, or when there is an infant formula that is otherwise adulterated or misbranded and that may present risk to human health. This notification shall be made, by telephone, to the Director of the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter. After normal business hours (8 a.m. to 4:30 p.m.) the FDA emergency number, 301–443–1240, shall be used. The manufacturer shall send a followup written confirmation to the Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and to the appropriate Food and Drug Administration district office specified in part 5, subpart M of this chapter.

[47 FR 17025, Apr. 20, 1982, as amended at 54 FR 24891, June 12, 1989; 61 FR 14479, Apr. 2, 1996; 66 FR 17358, Mar. 30, 2001; 66 FR 56035, Nov. 6, 2001; 69 FR 17291, Apr. 2, 2004]

PART 107—INFANT FORMULA

Subpart A—General Provisions

Subpart B—Labeling

Subpart C—Exempt Infant Formulas

Subpart D—Nutrient Requirements

Subpart E—Infant Formula Recalls

AUTHORITY: 21 U.S.C. 321, 343, 350a, 371.

SOURCE: 50 FR 1840, Jan. 14, 1985, unless otherwise noted.